

COMMISSION OF THE EUROPEAN COMMUNITIES

COM (74) 1101 final.

Brussels, 15 July 1974

Proposal for a
Second Council Directive
amending the Directive of 23 November 1970,
concerning additives in feedingstuffs.

(submitted to the Council by the Commission)

COM (74) 1101 final.

Justification

The Council Directive of 23 November 1970 (OJ No L 270 of 14 December, 1970, p.1) concerning additives in feedingstuffs has been generally regarded as an important step towards the harmonisation of legislation on this subject. This Directive not only regulates the use of additives in feedingstuffs, but also for the first time protects consumers in the Community against the excessive use of additives.

This tendency has been reinforced as the Directive has been applied.

When the original Directive was amended by the Council Directive of 28 April 1973 amending the Directive of 23 November 1970 concerning additives in feedingstuffs (OJ No L 124 of 10 May 1973, p. 17), and the procedure of the Standing Committee on Feedingstuffs was introduced to amend the Annexes, the Commission lost no time in seizing the opportunity of eliminating a number of antibiotics from Annex I (list of additives which are to be permitted throughout the Community). It also placed limitations and conditions on the use of a number of additives listed in Annex II (list of additives which may continue to be used temporarily within individual states).

On the other hand, the Commission further developed the Annexes with the purpose of improving the conditions for agricultural production. This process continues and up to the present, since the first reform of the provisions of the Directive in April 1973 there have been eight amendments to the Annexes. Further amendments are in preparation.

Experience gained in the course of making the above-mentioned amendments has shown, however, that the present procedure is still not completely satisfactory. According to the present concept, which is expressed in the Directive in force, Annex I was regarded as being the rule. Annex II was only set up in order to cover those substances on which agreement had not been reached when the Directive was passed, but which at the time were permitted in at least one Member States in accordance with principles which at least approximated to those set out in the Directive. The substances listed in Annex II were to be at the free disposal of individual states; however, a Member State which did not make use of this opportunity would, according to Article 14, have no right to bar animal products from its market on the pretext that substances from Annex II had been added in the country of origin.

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We were concerned here with materials which had been well known for a long time, the use of which had already been discontinued in some Member States, and partly with new materials, about which some Member States still wanted to gather information. Proceeding on the assumption that within five years following the issue of the Directive to the Member States, this situation would have resolved itself, the Council limited the applicability of Annex II accordingly. This time limit runs out during November 1975.

In fact, however, Annex II has already proved its general value as a phasing-in and phasing-out category. New materials or uses proposed since the Directive was issued have in fact almost without exception been first included in Annex II, because in every instance there were Member States which required a certain period of time to make their own tests on new materials from other Member States. Contrariwise, it was possible to eliminate a number of additives from Annex I only because they could be given a certain phasing-out period by including them in Annex II.

This procedure is now to be generalised, in that a time limit is to be put on the availability to the governments of Member States of materials listed in Annex II. Under this arrangement the time limit applicable to products listed at present in Annex II (end of 1975) will in practice remain unchanged, while time limits will in future be determined under Standing Committee procedure.

Since the revision of the Annexes has been retarded by the accession of the new Member States, the five-year limit is also to be extended by three years during which Member States may permit the use of substances belonging to groups of substances listed in Annex II which in part extend beyond those listed in Annex I. Care is still taken to ensure in the process that this authorisation does not extend to substances having a hormonal or anti-hormonal effect.

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It is further important that in future for all substances coming within Annex II evidence must also be produced showing that the substances are not harmful, that they can be analysed and that they fulfil medical and veterinary requirements.

Furthermore, the amending Directive should eliminate a point of contention which has arisen concerning the range of applicability. In fact the majority of Member States either proceed from the assumption or have recognised that the Directive applies to the feedingstuffs of all animals. One of the new Member States takes issue with this and for the moment wishes to apply the Directive only to productive animals.

There is much to be said for the usefulness of this kind of limitation, particularly with regard to pets, e.g. dogs, cats, canaries and ornamental fish. For this reason the Commission reserves the right to reconsider at an appropriate time whether a special regulation should not be drawn up for these animals, particularly in view of the fact that the composition of their feed is different from that of productive animals. On the other hand, wild animals, including most of those kept in zoos, should already be excluded from the area of application of the Directive.

The first amendment omitted to make the criteria of purity subject to Standing Committee procedure. Since it is here a question of technical implementing measures this should now be corrected. This procedure should also be applied when fixing criteria for the composition and character of permitted substances.

A number of further amendments to the Directive are purely technical in nature, but must be referred to the Council, because they are not established in the Annexes.

The essential provisions of the Directive should be incorporated in national legislation by 1 July 1975, so as to avoid any legal hiatus resulting from the lapse of the time limit for Annex II.

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The draft has been discussed with representatives of governments in the Commission Working Group on Feedingstuffs Legislation. It was found that a considerable measure of agreement existed on questions of principle.

Professional and consumer organisations throughout the Community have also been consulted concerning the draft. Again it was found that there was considerable agreement in favour of the draft.

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Draft of ... Second Council Directive of amending the
Directive of 23 November 1970, concerning additives in feedingstuffs

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,
and in particular Article 43 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament;

Whereas during the application of the Council Directive of 23 November
1970 (1), concerning additives in feedingstuffs, as last amended by the
Eighth Commission Directive of 26 February 1974 (2), amending the Annexes
of the aforesaid Directive, it appeared necessary to define the term
"animal";

Whereas it is advisable, in so far as this term relates to pets,
to examine subsequently if it would not be advisable to adopt a special
Directive in the case of feedingstuffs intended for these animals;

Whereas taking account of the amendments made by the Commission to the
Annexes, it is necessary to make some corrections and amendments of a
technical nature to the provisions of the Directive;

Whereas experience gained in relation to Annex II, which lists all the
additives which may be permitted by Member States at national level up to
the end of 1975, has shown that this Annex must, henceforth, act as a
buffer regulating the entry or the deletion of additives permitted at community
level (Annex 1); whereas such a measure necessitates the laying down of
special conditions governing the introduction of substances to Annex II;

(1) OJ No L 270, 14.12.1970, p.1
(2) OJ No L

Whereas, under Directive (EEC) No. 73/103 of the Council of 28 April 1973 (3), the adaptation of the Annexes to the growth of scientific and technical knowledge and hence the admission or deletion of additives has been brought under the procedure of the Standing Committee for Feedingstuffs; whereas, consequently, it would be advisable to specify likewise the criteria of purity for these substances in accordance with this same procedure,

Whereas, finally, it is also advisable to provide for the specification of criteria on the composition and quality of permitted additives,

Whereas experience obtained during the marketing of feedingstuffs containing additives demonstrates the necessity to improve the marking of these feedingstuffs which also include premixtures,

HAS ADOPTED THIS DIRECTIVE :

Article 1

The Directive of 23 November 1970 shall be amended as follows:

1. The following subparagraph shall be inserted in Article 2:

"g) Animals: The animals belonging to species which are normally kept and nourished by man".

2. The following text shall be substituted for the first sentence of Article 3 (4):

"4. Antibiotics (Annex I (A) and Annex II (A)) and growth promoters (Annex I (J) and Annex II (E)) may be mixed with only one single other antibiotic or growth promoter, unless the mixture to be produced is already provided for in those Annexes".

3. In the introduction to Article 3 (7) the words "except in the case of substances E 709 and E 712" shall be deleted.
4. In Article 3 (7) (B), the words "Zinc bacitracin and spiramycin and virginia mycin" shall be substituted for the words "All other antibiotics".
5. In Article 4 (1) (a), the word "eight" shall be substituted for the word "five". and the words "in Annex I or II" shall be substituted for the words in Annex I".
6. In Article 4 (1) (b), the words "during a period of five years following notification of this Directive" shall be deleted.
7. The following text shall be substituted for the text of Article 6 (1):

"1. The criteria concerning the composition, purity and quality of additives listed in this Directive shall be fixed, taking account of scientific and technical knowledge, in accordance with the procedure laid down in Article 16 (a)".
8. The following sentence shall be added to Article 6 (2) (B):

"The substance may be inserted in Annex II for a determined period, when the conditions of subparagraph A (b) ^{and (c)} are still satisfied".
9. The following subparagraph shall be added to Article 6 (2):

"C. A new substance or a new usage attributed to a substance may be inserted in Annex II only when conditions (b), (c) and (e) subparagraph A are satisfied and it can be assumed, taking account of available results, that the other conditions of subparagraph A are also satisfied".
10. In the introduction to Article 9 (1) the words "and growth promoters (Annex I (J))" shall be inserted after the words "Vitamins D (Annex I (H) No. 1)".

- "Article 11a

- a) that the premixture is not intended for direct animal consumption.
- b) the maximum permitted content of the premixture in the daily ration.

17. A new column, entitled "Period of authorisation", shall be added to Annex II. The date of "31 December 1975" shall be entered in this column for all the additives listed at present in the Annex.

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and the other side of the international border.

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1 July 1976.

Article 2

Member States shall bring into force the laws, regulation and administrative provisions necessary to comply :

- a) by 1 July 1975 at the latest with Article 1 (9) (6) (7) (8) and (9) ;
- b) by 1 July 1976 at the latest, with the other provisions of this Directive.

Article 3

This Directive is addressed to the Member States.
